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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,048	01/11/2002	Stephen J. Brand	24492-006	8033

7590

02/08/2005

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EXAMINER

HUNNICUTT, RACHEL KAPUST

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/044,048

Applicant(s)

BRAND, STEPHEN J.

Examiner

Rachel K. Hunnicutt

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36,37,41,42,50-52 and 69-96 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36,37,41,42,50-52 and 69-96 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

RESPONSE TO AMENDMENT

Applicant's amendment filed October 22, 2004 is acknowledged. Claims 1-35, 38-40, 43-49, and 53-68 have been canceled. Claims 37, 41, 42, and 50 are amended. Claims 70-96 are new. Claims 36, 37, 41, 42, 50-52, and 69-96 are pending and under consideration. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections/Objections Withdrawn

The objection to the specification regarding the priority claim is withdrawn in response to Applicant's amendment to the specification.

The objection to the specification regarding the use of trademarks is withdrawn in response to Applicant's amendments to the specification.

The objection to claim 38 for containing a typographical error is withdrawn in response to Applicant's cancellation of the claim.

The objection to claims 29-31 for containing typographical errors is withdrawn in response to Applicant's cancellation of these claims.

The rejection of claims 38, 43-49, and 64 under 35 U.S.C. 112, second paragraph, regarding the term "short duration" is withdrawn in response to Applicant's cancellation of these claims.

The rejection of claims 29-32 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter with applicant regards as the invention, is withdrawn in response to Applicant's cancellation of these claims.

The rejection of claims 24-28, 33-35, and 64 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,885,956, is withdrawn in response to Applicant's cancellation of these claims.

The rejection of claims 24-28, 33-35, and 64 under 35 U.S.C. 102(f) is withdrawn in response to Applicant's cancellation of these claims.

Claim Rejections Maintained/New Grounds of Rejection

Claim Rejections - 35 USC § 112

Claims 36, 37, 41, 42, 50-52, and 69-96 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims encompass methods of administering a "synthetic gastrin derivative" and a "recombinant modified EGF". These terms are not defined in the specification, and one skilled in the art would not be reasonably apprised of the scope of the invention. The skilled artisan would not know what molecules Applicants intended the claims to encompass.

Claims 37, 52, 71, and 96 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are rejected to the extent that they are drawn to synthetic gastrin derivatives having a leucine substituted at position 15 and recombinant modified EGFs having a neutral amino acid substituted at position 51. Although Applicant refers to the residues by numbers, the numbers of the residues are not definite. It is not known what position constitutes residue number 15 or 51. In order to be definite, Applicant must refer to residue positions within a specific sequence.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 36, 41, 42, 51, 69, 70, 78-89, and 91-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nardi *et al.* (U.S. Patent No. 5,885,956, submitted by Applicant in April 5, 2002 IDS). The claims are drawn to methods for treating subjects having insulin-insufficient diabetes by administering a synthetic gastrin derivative and a recombinant modified EGF, and then repeating administration of the compounds at the end of the remission of the diabetes, *i.e.* when the symptoms start to reappear.

Nardi *et al.* teach a method for treating diabetes mellitus by administering a composition comprising a gastrin/CCK receptor ligand and an EGF receptor ligand in an amount sufficient to effect differentiation of pancreatic islet precursor cells to mature insulin-secreting cells. According to Nardi *et al.*, suitable dosage ranges for intravenous administration are about 20-500 micrograms of active compound per kilogram body weight. Suitable dosage ranges for intranasal administration are generally about 0.01 pg/kg body weight to 1 mg/kg body weight. The same composition is being administered for the treatment of the same disease, but Nardi *et al.* do not teach repeating the administration of the compounds at the end of the remission of the diabetes.

It would have been obvious to one skilled in the art to repeat the administration of the therapeutic composition once symptoms began to reappear. Moreover, optimization of conditions through routine experimentation is not considered to be an advancement of the useful arts. MPEP 2144. See *In re Hoeschele*, 406 F. 2d 1403, 160 USPQ 809 (CCPA 1969) ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."). The skilled artisan would have expected the modified method to be equally effective in treating diabetes mellitus.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 36, 42, 51, 69, 70, 72, 73, 85-89, and 91-95 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-20, 22, 24-25, and 32-33 of copending Application No. 10/843,780. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '780 application teaches methods and compositions for treating diabetes mellitus. The methods

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include administering to a patient a composition providing a gastrin/CCK receptor ligand and an epidermal growth factor receptor ligand in an amount sufficient to effect differentiation of pancreatic islet precursor cells to mature insulin-secreting cells. The specification teaches that one means for monitoring the efficacy of the treatment is monitoring the blood glucose level.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

NO CLAIMS ARE ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel K. Hunnicutt whose telephone number is (571) 272-0886. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RKH
2/7/05


JANET ANDRES
PRIMARY EXAMINER